IV. Parameters Setting and Preventive Maintenance

IV. Parameters Setting and Preventive Maintenance

The FMS2000 requires minimal service and care. Preventive maintenance should be performed regularly to optimize performance and reduce the likelyhood of down-time. Listed below are routine maintenance (as needed), periodic maintenance (at least once a year), and parameters setting. The instrument does not need regular calibration.

WARNING!

Practice standard precautions when handling blood products. Treat all blood as if it were infected and clean up all spills immediately.

WARNING!

Test leakage current routinely to insure against electrical shock hazard.

CAUTION:

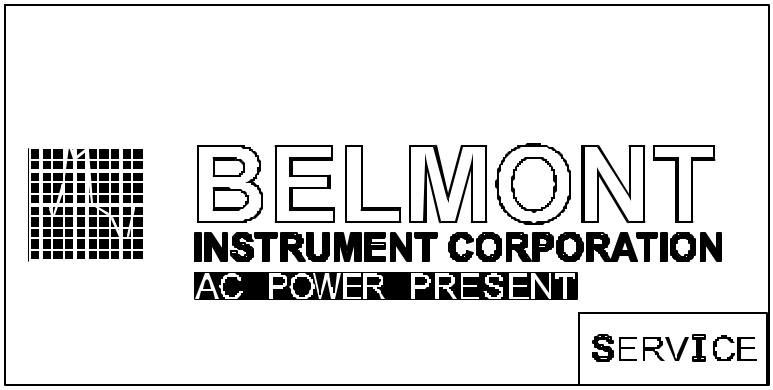
Turn the system to STANDBY and unplug the power cord before cleaning to avoid electric shock.

A. SYSTEM SETUP

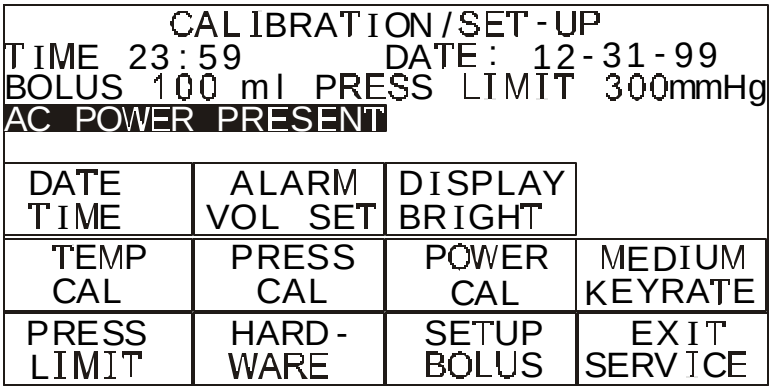
Changes in system setup can be made to:

- Date and time: Set the real time clock and date
- Audible alarm volume: Set the audible alarm volume level
- Display brightness: Change the display brightness
- Key Rate: Set touch key sensitivity
- Bolus volume: Set the bolus delivery volume
- Pressure limits for High Pressure alarm: Set the maximum allowable in-line pressure. The possible setting range from 100 - 300 mm Hg.

Parameter Setup changes are performed in the Service mode.

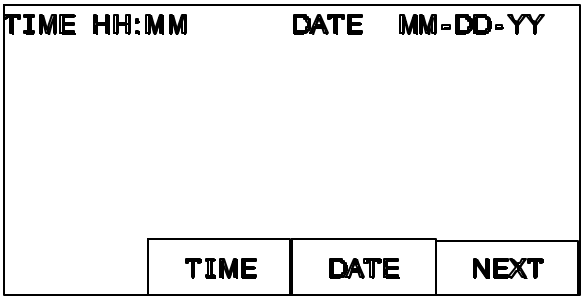


Press the SERVICE key to access Calibration/Set-up mode. This key appears on the BELMONT logo screen only at system powered-up. This screen remains active for 4.5 seconds before the system enters the Prime mode.



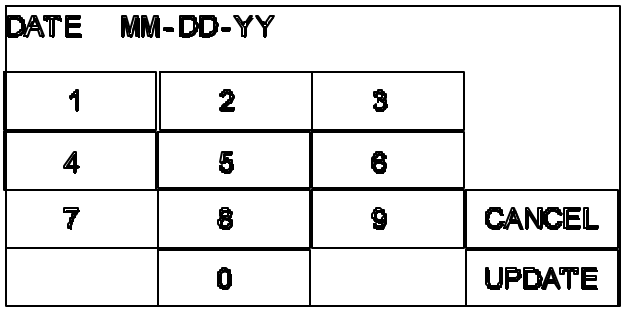
1. Date/Time

Press DATE TIME to set the time and date. Press either the TIME or DATE key.

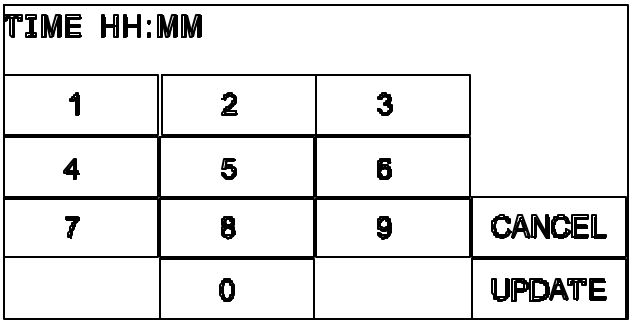


Screen after pressing DATE TIME key

A numerical key pad will be displayed. Enter the appropriate time or date information. Enter the appropriate time in 24 hour clock format (i.e. 1:00 PM = 13:00). CANCEL will erase the entered value and return to the previous Date Time screen. Press UPDATE to save the new value and return to the previous DATE TIME key screen. Press NEXT to return to the Calibration/Set-Up screen.



Screen after pressing DATE



Screen after pressing TIME

2. Alarm Volume

ALARM VOL SET is used to set the volume level of the audible alarm. There are seven levels of alarm volume. Each time the key is pressed, a tone will sound to indicate the present alarm volume level.

3. Display Brightness

There are nine levels of display brightness. Press DISPLAY BRIGHT to change the present level of brightness to the next level.

4. Key Rate

This key sets up the sensitivity of the touch keys. There are three different levels of sensitivity; Fast , Medium and Slow. The current level of sensitivity is indicated on the key itself. The Fast setting requires the least amount of time for a key when touched to be accepted as an input. The Medium setting requires more time and the Slow key requires the most time and makes the touch keys least sensitive. **The key sensitivity is set at factory to Medium**.
Note that this key changes the time required to depress a key for stroke to be recognized. The pressure required is not affected.

5. Bolus Volume

The bolus volume can be set between 100 to 500 and can be changed by 50 ml each time SETUP BOLUS is pressed. The current bolus volume is indicated at the BOLUS status line in the Calibration/Setup screen. The bolus volume is also displayed within the BOLUS key in the Infuse screen (see Chapter II under Main Infuse screen).

6. Pressure Limit

The user can set the maximum allowable in-line pressure. The possible setting range from 100 to 300 mm Hg. The current pressure limit value is displayed on the PRESS LIMIT status line on the Calibration/Set-Up screen. Press and hold the key to change the limit in increments of 50 mm Hg. During infusion, the system keeps the pressure in the line under the pressure limit by reducing the infusion rate as the in-line pressure approaches the pressure limit. **The system automatically resets the pressure limit to 300 mm Hg, at power-up.**

B. PREVENTIVE MAINTENANCE SCHEDULE

Schedule 1: should be performed by either the Clinical User or a Biomedical Technician (BMET).

Schedule 2: should be performed by either a BMET or other qualified service personnel.

Schedule 1

To be performed by either the Clinical User or a Biomedical Technician (BMET).

Routine Maintenance	Interval		
	Before or After each Use	Every Month	Every 6 Months
1. Clean and/or Disinfect Exterior, if necessary.	●		
2. Clean Fluid Out and In-Line Air Detector.	●		
3. Check the Power Cord.	●		
4. Clean Temperature Probes.	●		
5. Check/Clean the Fan Guard.		●	
6. Check the System Seal.			●
7. Check Instrument Door and Ceramic Disk.			●
8. Check the Rubber Feet.			●

Schedule 2

To be performed by either a BMET or other qualified service personnel.

Required Test/Verification	Interval	
	Every 6 Months	Every Year
1. Perform Visual Inspection.	●	
2. Perform System Operational Check-Out, including the Audible Alarm Test.	●	
3. Check the battery for rated voltage and check battery run time.	●	
4. Perform Electrical safety Test.		●
5. Hardware Verification.		●
6. Clean Pump Head.		●

C. ROUTINE MAINTENANCE

1. Clean and/or Disinfect Exterior

Clean the outside surfaces of the system and inside the door after each use.

a. Turn the pump to standby and unplug the power cord.

b. Wipe the surface with a cloth moistened with water or isopropyl alcohol.

Note: Avoid the use of acetone or other solvents that might damage the surface.

c. To remove dried blood and disinfect the pump, clean them with hydrogen peroxide or a mild bleach solution and dry.

d. Also clean around the door hinges, making sure the door is pushed all the way down inside the hinges.

2. Fluid Out and In-Line Air Detectors

Keep the fluid out and air detectors clean and dry. If they become dirty or wet, clean with a moistened Q-tip and dry. Air detector surfaces are delicate. Use care when carrying out this procedure.

3. Power Cord

Inspect the power cord along its length and connectors for cuts and breaks. Replace power cord if damaged (replacement P/N 118-00096 for US and P/N 118-00085 International).

4. Temperature Probes

Keep the probe sensors clean and dry. If they become dirty or wet, clean with a moistened Q-tip and dry. Use care not to damage the sensor surface.

5. Fan Guards

Inspect the fan guards, on the bottom of the unit, for debris that might impede air flow. Remove guards by unscrewing the 4 retaining screws and clean, with soap and water, if necessary. Make certain the guards are not damaged (replacement P/N 399-00033). Let the fan guards dry before reinstalling.

6. Seals

Inspect the seal around the unit to make certain it is in good condition. Check also the seal around the touch screen and ceramic disks. Use Dow Corning 732 multipurpose RTV sealant or equivalent if needed to maintain fluid re

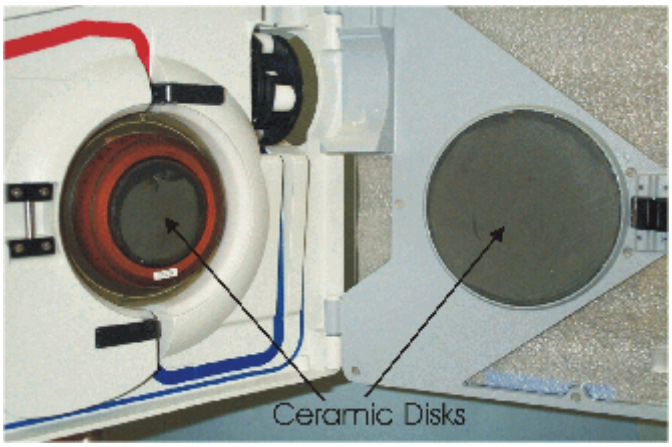
7. Instrument Door and Ceramic Disks

The instrument door must fit properly for the system to operate correctly. The platen part of the roller pump is located on the door. The platen must line up properly with the pump.

a. Check hinges for blood build-up, clen any dried blood from hinges area. Be sure that door is seated completely down on the hinges.

b. Check plastic rivets and door integrity. Make sure that the door frame is not bent. Replace, if bent.

c. Inspect the ceramic disks on the door and in the center of the unit for cracks. Return to manufacturer for replacement if they are damaged.



8. Rubber Feet

Inspect the rubber feet on the bottom of the unit for cracked or missing rubber feet. Replace if necessary (replacement #599-00314 Rubber feet & #510-00349 6-32 x 1 1/8" screw).

D. TEST/SYSTEM OPERATIONAL CHECK-OUT

The device should be serviced periodically, in accordance to schedule 1 and 2, by a qualified technician. Prior to performing the battery run test, plug the system into an AC outlet for at least 8 hours to fully charge the batteries.

Material Required:

- FMS2000 Disposable
- Bio-Tek Safety Analyzer or equivalent
- Saline or other crystalloid for testing
- 2 liters of 35-42° C fluid
- Manometer (2 mm Hg resolution)
- Pressure source
- Digital Thermometer with thermocouple (0.1°C resolution)
- Graduated cylinders (ASTM Class B accuracy)
- Timer
- Tachometer (optional)

1. Visual Inspection

a. Door Open/Right Hand Side:

i. Check that air and fluid out detectors are clean.
ii. Check that all the plastic push pins on the door are in-place.
iii. Check that the valve pincher set screw is tight.
iv. Check that there are no cracks in the ferrite on either the door or the right hand side.
v. Check that the pressure transducer diaphragm has no tears or rips.
vi. Check that each pump roller spins freely. If not, remove and clean.
vii. Check that the door is pushed all the way down and there is no dried blood or fluid inside or around the hinges.

b. Back:

i. Check that the AC connector (IEC connector) is clean. If there is some saline residue, clean.

c. Verify Latch/Unlatch Mechanism:

i. Check the rubber pads on the pole clamp assembly. If they feel smooth, clean and scrub with isopropyl alcohol.
ii. Mount and unmount the system on an IV pole, verify that the latch and unlatch work properly and the system will not move down the pole unexpectedly.

2. System Operational Check-Out

a. Install Disposable set.

b. Turn power switch ON. Wait for PRIME screen to appear.

c. Close bag clamps. Hang and spike fluid bag.

d. Open bag clamp(s). Press PRIME to prime the system (circulate 100 ml of fluid at 500 ml/min.) Prime volume (100 ml) countdown is displayed on screen. Stop automatically when countdown reaches 0 ml.

e. Press PT. LINE PRIME once to pump at 50 ml/min or press and hold to pump at 200 ml/min. Press STOP when line is free of air bubbles.

f. Press INFUSE to start infusion at 10 ml/min. Press INFUSE RATE ▲▼ to change flow rate.

g. Remove the power cord. Verify that the system automatically switches to battery when AC is disconnected. BATTERY NO HEATING message displays to indicate the system is now in battery mode and heating is suspended.

h. Connect back to AC power and verify the operation is uninterrupted. Adjust the flow rate by pressing INFUSE RATE ▲▼.

i. Infuse until the fluid bag is empty, verify that the system stops pumping and sounds an audible alarm with 'FLUID OUT' message displays on screen.

3. Battery Run Time Test

a. Prior to performing the battery run test, plug the system into an AC wall outlet for at least 8 hours to fully charge the batteries.

b. Follow directions in Step 2, a-g. Infuse at 50 ml/min. Start the timer.

c. The system should run for at least 30 minutes with fully charged battery. If not, replace the batteries.

4. Electrical Safety Test - Leakage Current

Equipment required: Bio-Tek Safety Analyzer, Model 370 or equivalent
2 Liters of room temperature saline

Setup: Plug the FMS2000 into AC outlet on the front of Bio-Tek Safety Analyzer.

> **CAUTION:**
>
> Before applying voltage to Bio-Tek, make sure input line voltage is correct for the **VOLTAGE OF UNIT UNDER TEST**.

Switch found on the back of Bio-Tek: 115 or 230 V

a. Earth Leakage Currents:

i. Plug the Bio-Tek into an appropriate power source, turn Bio-Tek power ON. FMS2000 power switch To Standby.

ii. Switch selector on Bio-Tek to CHASSIS (µA). Connect a single red lead to the SINGLE LEAD input jack, and attach large clamp to equipotential ground terminal on the FMS2000.

iii. Record the leakage current displayed for each of the following conditions, with Neutral switch in NORM position. Tests should be performed in the following order.

Polarity - NORM;	Ground - NORM
Polarity - REVERSE;	Ground - NORM
Polarity - REVERSE;	Ground - OPEN
Polarity - NORM;	Ground - OPEN

iv. Repeat the first two (Normal Polarity and Reverse Polarity - Grounded) with Neutral switch in OPEN position.

v. Install the disposable set and prime with saline and proceed to the Infuse screen. Press STOP to set the pump at 0 ml/min, not heating or pumping.

vi. Repeat iii & iv with the FMS2000 in ON mode (power switch ON, infuse screen displayed, not pumping or heating).

vii. Repeat iii & iv with the FMS2000 infusing and heating at 750 ml/min.

viii. All measurements should be <300 µA (for Domestic unit) and <500 µA (for 230 V unit) .

b. <u>Patient Leakage Current:</u>

i Install the disposable set and prime with saline and proceed to the Infuse screen.

ii. Attach 12 to 16 gauge stainless steel cannula to the end of patient line and attach the Bio-Tek large clamp to the cannula.

iii. Prime the FMS2000 with saline. Make sure that the entire patient line including the cannula has been primed.

iv. Repeat a.iii, and a.iv with the FMS2000 in the STANDBY, ON, and pumping at 750 ml/min modes.

v. Maximum leakage allowable is as follows:

With NORMAL NEUTRAL

Normal Polarity - Grounded (10 µA)

Reverse Polarity - Grounded (10 µA)

Reverse Polarity - Not Grounded (50 µA)

Normal Polarity - Not Grounded (50 µA)

With OPEN NEUTRAL (Note: the system automatically switches to battery infuse at 50 ml/min)

Normal Polarity - Grounded (50 µA)

Reverse Polarity - Grounded (50 µA)

5. Hardware Verification

Properly install and prime the disposable set (see Chapter II for installation of the disposable, prime, and infuse) before beginning the Hardware verification process.

The hardware mode verifies:

a. Valve Operation
b. Fluid Out and Air Detectors
c. Battery Voltage
d. Flow Rate (pump speed)
e. Input and Output Temperature Probes, and
f. Pressure sensor

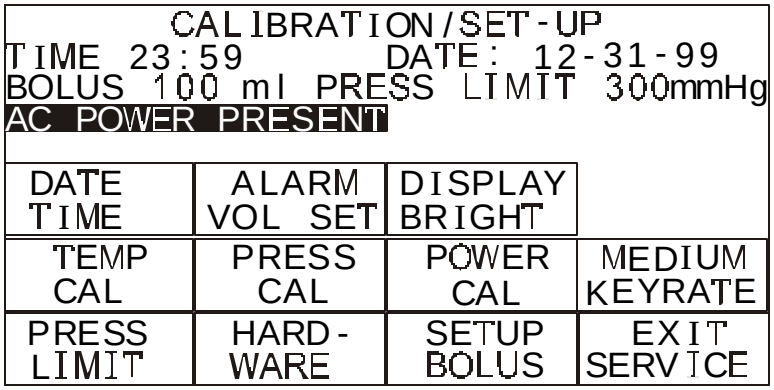
A password is required to access this screen, to insure that this mode is not accessed accidentally.

Press the SERVICE key, at power up, to access service screen. This screen remains active for 4.5 seconds before the system enters the Prime mode screen.

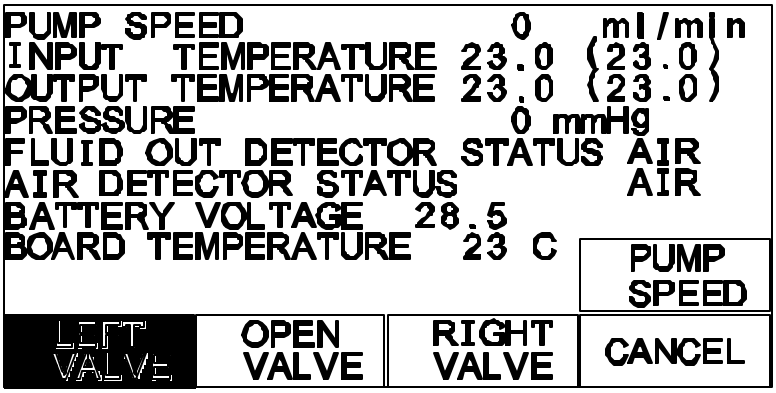
WARNING!

Do not access hardware verification while the instrument is patient connected.

- Press HARDWARE from the Calibration/Set-Up screen.
- Enter the Password 013192.



Calibration/Setup screen



Hardware Status Screen

Status Line	Reading
Pump Speed	0, 10, 100, 500 and 750 ml/min
Input Temperature	Temperature in °C, probe ambient reference in parentheses
Output Temperature	Temperature in °C, probe ambient reference in parentheses
Pressure	Pressure in mmHg
Fluid Out Detector Status	Air or Fluid
Air Detector Status	Air or Fluid
Battery Voltage	Battery charge level in volts
Board Temperature	Temperature of the circuit board inside the case.

Function Key	Action
PUMP SPEED	Change pump speed.
LEFT VALVE	Move the valve to the left or recirculate position.
OPEN VALVE	Move the valve to the middle or load position.
RIGHT VALVE	Move the valve to the right or infuse position.
CANCEL	Exit Hardware status and return to the Calibration/Set-Up screen.

Hardware Verification:

a. Valve

i. Press the LEFT VALVE, confirm that the valve wand (valve pincher) move to the left.

ii. Press OPEN VALVE, confirm that the valve wand move to the middle position.

iii. Press RIGHT VALVE, confirm that the valve wand (valve pincher) move to the right. Leave the valve into the LEFT VALVE position before continuing to the next step.

b. Fluid Out and Air Detectors

i. Confirmed that the Fluid Out Detector and the Air Detector status lines display FLUID when the system is primed and no air is in the detectors.

ii. Open the door and pull out the tubing from the detectors. Close the door and confirm that the status line display AIR when the tubing is removed from the sensor.

c. Battery Voltage

Unplug the unit from the wall outlet, check 'Battery voltage' displayed in HARDWARE screen, should be approximately 24 volts. If not, recharge the battery for at least 8 hours and recheck. Plug the unit back into the wall outlet.

d. Flow Rate

The flow rate can be verified by actually measuring the flow using a graduated cylinder and timer or by using a tachometer. Choose the method that best serves your setup.

Directly measure the flow:

i. Make certain the patient line and entire disposable is fully primed before measuring. Set the pump speed to 10 ml/min. Press RIGHT VALVE to set the valve into the infuse position and fill the patient line. Use a graduated cylinder to measure flow at the patient line for ten minutes and verify the average flow rate over that period. The volume collected should be 100 ± 25 ml for an averaged flow rate of 10 ± 2.5 ml/min.

ii. Press PUMP SPEED again to change the pump speed to 100 ml/min and measure the flow with a graduated cylinder for one minute. The accepted tolerance is 100 ± 10 ml/min.

iii. Press once more to change speed to 500 ml/min and repeat the measurement. The accepted tolerance is 500 ± 50 ml/min.

Measure by using a tachometer:

i. Close the door. Set the pump speed to 10 ml/min. Use a tachometer to measure the rotational speed of the pump head. The accepted tolerance is 1.95 rpm ± 25%.

ii. Press PUMP SPEED again to change the pump speed to 100 ml/min. The accepted tolerance is 19.65 rpm ± 10%.

iii. Press once more to change speed to 500 ml/min, the maximum speed setting and repeat the measurement. The accepted tolerance is 97rpm ± 10%.

e. Input and Output Temperature Probes

Prepare at least 2 liters of 37-43 °C fluid

i. Connect the fluid supply to the disposable. Remove the patient line and insert the thermocouple into the patient line connector as close to the heat exchanger as possible.

ii. Press the RIGHT VALVE key to set the valve to the infuse position. Open the fluid supply and set the pump speed to 500 ml/min.

iii. Let the temperature stabilize, wait at least 2 minutes. The INPUT TEMPERATURE and OUTPUT TEMPERATURE value readings (the values not between the parentheses) should be within. (2 °C)

iv. Compare the numbers displayed to the thermocouple reading. The accepted tolerance is 1°C for fluid temperature between 30 °C to 40 °C and 2°C outside this range.

v. Press PUMP SPEED to set the pump speed back to 0 ml/min.

vi. Press CANCEL to return to the Calibration/Set-Up screen.

f. Pressure Transducer

> **WARNING!**
>
> Do not apply excessive pressure to the pressure chamber or pressure transducer. The pressure transducer is a precision electromechanical device and can be damaged with excessive force. **Do not use the system if the pressure transducer is damaged**.

i. **Inspect the pressure transducer for damage. Make certain the surface of the transducer is not cut or punctured. The pressure transducer must be replaced if the surface is damaged.**

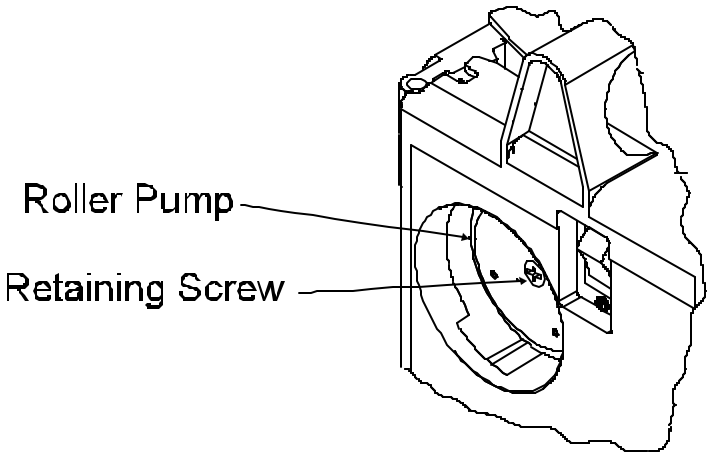
ii. Make certain the pressure chamber is properly installed (see Chapter II: Installing the Disposable) and the flow path is not blocked.

iii. Make certain the fluid is warm (37-42° C). The pressure chamber of the disposable is less compliant when it is at room temperature. **Verification must be performed with a warm disposable.** If the fluid is not warm, go to the Main Infuse screen and warm the fluid and disposable by pressing the RECIRC key (Chapter II: Main Operating Screen: Recirculating Mode). Let the fluid recirculated for at least two minutes in AC power before returning to the Hardware mode for verification.

iv. In the Hardware mode, close the door, the bag clamps and block the air vent on top of the reservoir chamber. Disconnect the patient line and connect the pressure source to the luer fitting at the patient line port of the disposable set and apply pressure while monitoring the amount of pressure with a manometer.

v. Verify the accuracy of the pressure transducer. Apply 300 mm Hg into the disposable. The pressure status line should read 300 mm Hg (± 50 mm Hg). Repeat the same pressure verification for 200 and 100 mm Hg.

6. Clean Pump Head



The pump head can be removed and cleaned if needed.

a. Turn the pump to STANDBY and unplug the power cord.

b. Unscrew the retaining screw that holds the pump head.

c. Remove the pump head and clean with water and soap. Hydrogen peroxide or a mild bleach solution can be used to disinfect.

e. Let pump head dry before replacing and make certain the pump head is securely fastened with the retaining screw.

f. If the pump head squeaks, spray the roller with Heavy Duty Pure Silicone.

E. CHECKLIST

FMS2000 S/N:	Tested By:	Date

Equipment Used:	Safety Analyzer S/N:		Cal Due Date:
	Pressure Source S/N:		Cal Due Date:
	Thermometer S/N:		Cal Due Date:
	Tachometer S/N:		Cal Due Date:

		Results	
1.	**Visual Inspection** a Right Hand Side b. Back c. Latch/Unlatch		✓ **if OK**
2.	**Operational Check-Out** d. PRIME e. PT. LINE PRIME f. INFUSE ▲▼ g. AC to DC Switch over h. DC to AC switch i. FLUID OUT audible alarm		✓ **if OK**
3.	**Battery Run Test**		>30 min.
4.	**Electrical Safety Check** (See attached results sheet) a. Earth Leakage Current b. Patient Leakage Current		✓ **if OK**
5.	**Hardware Verification** a. Valve Operation b. Fluid Out and Air Detectors c. Battery Voltage d. Flow Rate e. Input and Output Temperature Probes f. Pressure Sensor		✓ **if OK**
6.	**Clean Pump Head**		✓ **if OK**

Electrical Safety Test - Leakage Current Results Sheet

a. Earth Leakage Currents (all measurements are in µA)

	Polarity - N; Ground - N	Polarity - R; Ground - N	Polarity - R; Ground - O	Polarity - N; Ground - O
Unit in STANDBY • Neutral - NORM				
• Neutral - OPEN				
Unit in ON, not pumping • Neutral - NORM				
• Neutral - OPEN				
Unit in ON, infusing @ 500 ml/min. • Neutral - NORM				
• Neutral - OPEN				

b. Patient Leakage Currents (all measurements are in µA)

	Polarity - N; Ground - N	Polarity - R; Ground - N	Polarity - R; Ground - O	Polarity - N; Ground - O
Unit in STANDBY • Neutral - NORM				
• Neutral - OPEN				
Unit in ON, not pumping • Neutral - NORM				
• Neutral - OPEN				
Unit in ON, infusing @ 500 ml/min. • Neutral - NORM				
• Neutral - OPEN				

F. HARDWARE CALIBRATIONS

At each startup the system automatically checks if the temperature probe, pressure sensor and the power module have lost calibration information. If any one of the hardware parameters has been corrupted, the system goes directly into the Calibration/Set- Up screen upon boot up. The TEMP CAL, PRESS CAL and/or POWER CAL key(s) will light up to indicate that calibration is needed. The system will not exit the Calibration/Set-Up mode until it is calibrated. In addition, the current time and date, bolus setup volume and the presence of AC or DC power are displayed.

Calibration of the system is done at the factory. A password is required to calibrate the system to insure that this mode is not accessed accidentally.

CAUTION

The instrument does not need regular hardware calibration. Calibrate the instrument only after verifying that it is operating outside accepted parameters or when the calibration information has been corrupted.

Calibration or testing of the hardware in this mode includes:

1. Pressure sensor
2. Temperature probes
3. Power module and pump

WARNING!

Do not access hardware calibration while the instrument is patient connected.

Materials needed for calibration:

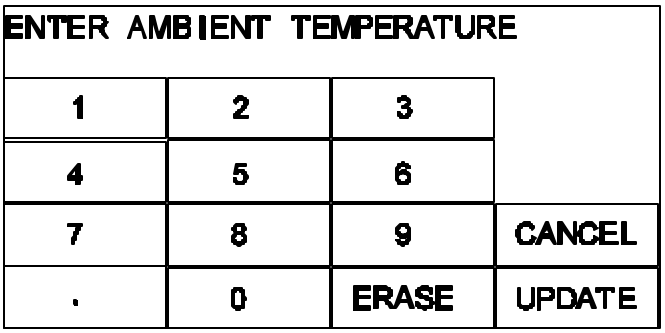
- New disposable set
- Manometer or gauge (up to 300 mm Hg, 2 mm Hg resolution)
- Pressure source
- Thermometer with thermocouple with readout resolution to 0.1 °C.
- Graduated cylinder (ASTM Class B accuracy)
- Timer

1. Temperature Probes Calibration

Prepare 4 liters each of different temperature fluid at : 1 - 7 °C; 17 - 23 °C; and 37 - 43 °C before beginning the temperature calibration.

The system must left in STANDBY or unplugged at a stable ambient temperature for at least two hours before performing a temperature probe calibration. Do not leave the system ON. This allows the reference in the temperature probe to equilibrate. The system will not temperature calibrate if the probes are not in equilibrium.

- Properly install the disposable set (see Chapter two: Installing the Disposable). Turn power ON. Press the SERVICE key when it appears at the logo screen at startup.
- Press TEMP CAL to begin calibration.
- Enter password 013192.
- Enter the ambient temperature measured to the nearest 0.1°C. If a mistake was made entering the value, press ERASE to reenter. Press UPDATE to save the ambient temperature value.



Numerical key pad to enter ambient temperature in TEMP CAL.

- Connect two (2) at least one liter bags of 4 ± 3 °C fluid to the disposable. A large reservoir of fluid will help limit the need to changing the bags often and limit temperature fluctuations during the calibration procedure. Remove the patient line and insert the thermocouple into the patient line connector as close to the heat exchanger as possible.
- Press NEXT to pump the fluid at 500 ml/min into the disposable. If the procedure has to be abandoned press EXIT and the system will return to the Calibration/Set-Up screen.
- Keep fluid filled in the disposable set by attaching more fluid filled bags while the temperature of the disposable set equilibrate.
- After a minimum of two minutes a numerical key pad will appear. Wait until the temperature reading stabilizes on the thermometer then enter the

temperature of the disposable. Enter the actual measured value which must be between 1 °C and 7 °C (4± 3 °C). Do not enter the nominal 4 °C value. Press UPDATE to save the value and continue to the next temperature. If the temperature was still fluctuating when UPDATE was pressed, the system will not update and continue to wait until the temperature stabilizes.

- Continue with the same procedure for the 20 ± 3 °C and the 40 ± 3 °C fluid. In each case enter the actual value measured within the specified range. For example, the measured value at the nominal 40 °C level must be between 37 °C and 43 °C for the calibration to be valid.
- After the last temperature fluid, 40 ± 3 °C is updated, the system will return to the Calibration/Set-Up screen.
- Press HARDWARE to check on Hardware status.
- Enter password 013192.
- Add more 40 ± 3°C fluid supply to the disposable.
- Press the RIGHT VALVE key to set the valve to the infuse position.
- Press the PUMP SPEED three times to set the flow rate to 500 ml/min
- Let the temperature to stabilize, wait at least 2 minutes. The INPUT and OUTPUT TEMPERATURE probe readings should be similar and stable (the values not between the parentheses).
- Compare the numbers displayed to the thermometer reading. The accepted tolerance is 1°C for fluid temperature between 30 °C to 40 °C and 2°C outside this range.
- Repeat with the 20 ± 3 °C and 4 ± 3 °C fluid.
- Finally press PUMP SPEED to set the pump speed back to 0 ml/min.
- Press CANCEL to return to the Calibration/Set-Up screen.
- The system is temperature calibrated and verified.
- After a temperature calibration has been completed, a power calibration should be performed. See Power Module and Pump Calibration in this chapter.

2. Pressure Transducer Calibration

Prepare 1 liter of 37-43 °C fluid

- Inspect the pressure transducer for damage. Make certain the surface of the transducer is not cut or punctured. The pressure transducer must be replaced if the surface is damaged.

- Properly install the disposable set (see Chapter two: Installing the Disposable). Center the disposable's pressure chamber in the pressure chamber cavity of the machine. Make certain that the pressure chamber of the disposable set is in good contact with the pressure transducer.

- Turn power ON. Press the SERVICE button when it appears at the logo screen at system startup.

- Press HARDWARE and enter the password 013192.

- Attach fluid (37-43 °C) to the disposable set and open the clamps. Make certain the fluid is warm. The pressure chamber of the disposable is less compliant when it is at room temperature. **Calibration must be performed with a warm disposable.** Press PUMP SPEED three times to set flow rate to 500 ml/min to prime the system with warm fluid.

- Press the RIGHT VALVE key to set the valve to the infuse position and continue to warm up the disposable to a steady temperature close to the temperature of the fluid. Check that the pressure chamber is completely filled with fluid.

- Press CANCEL to exit back to the Calibration/Set-Up screen when done.

- Press PRESS CAL and enter the password 013192 from the Calibration/Set-Up screen to initiate the calibration procedure.

- Close the bag clamps and block the air vent on top of the reservoir chamber. Disconnect the patient line and connect the pressure source to the luer fitting at the patient line port of the disposable set and apply pressure while monitoring the amount of pressure with a manometer.

- Apply 100 mm Hg of pressure. Press UPDATE to accept the 100 mm Hg calibration point.

- Apply 258 mm Hg of pressure. Press UPDATE to accept the calibration point. The system will return to the main Calibration/Setup screen.
- Press HARDWARE and enter password to access the Hardware mode.
- Press OPEN VALVE to set the valve in the middle position.
- Verify that the system is properly calibrated. Apply 258 mm Hg into the disposable. The pressure status line should read 258 mm Hg (± 25 mm Hg).
- Repeat the same pressure verification for 100, and 300 mm Hg.
- The system is now pressure calibrated and verified.

3. Power Module and Pump Calibration

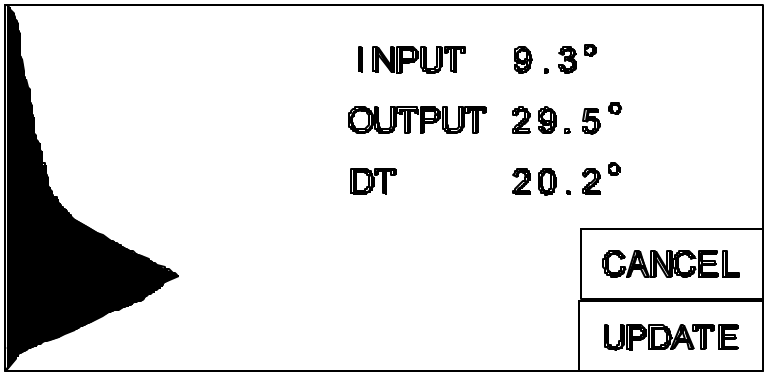
Prepare a minimum two liters of water, having a temperature less than 10 °C before starting the power module and pump calibration.

> **CAUTION**
>
> Before the power module can be calibrated, be certain that the temperature probes are calibrated and functioning properly, verify in hardware status. Perform a temperature probe calibration before continuing with the power module calibration, if necessary.

- Properly install the disposable set (see Chapter two: Installing the Disposable). Turn power ON. Press the SERVICE key when it appears at the logo screen at startup.
- Connect two (2) one liter or larger bags of fluid to the disposable. A large reservoir of fluid will help limit the need to changing the bags often .
- **Determine the actual maximum flow rate of the disposable first**: Press HARDWARE from Calibration/Set-UP screen.
- Enter password 013192.
- Open bag clamps and prepare to prime the disposable. Press PUMP SPEED three times to set pump speed to 500 ml/min. This will recirculate the system with fluid and prime the main fluid circuit. Check that the disposable is completely filled with fluid. Press RIGHT VALVE to set the valve into the infuse position and prime and fill the patient line.
- When the patient line is completely primed, measure the flow with a graduated cylinder for one minute. When completed, press PUMP SPEED key once to set the flow rate to 0 ml/min and stop the pump. Press CANCEL to exit and return to the Calibration/Set-Up screen. Record this flow rate. The flow rate should be 500 ml/min ± 10%. If the flow is not within specification check that the tubing in the pump head is well seated in between the rollers and housing. The tubing should not be kinked.
- Press POWER CAL.
- Enter password 013192.
- Enter the flow rate that was previously measured. Press UPDATE to continue.

- Prime: The system primes the disposable set with 100 ml of fluid before automatically determining the proper power module settings for the unit. To abort the procedure, press CANCEL. Two flow rates are used during calibration, 500 ml/min first followed by 10 ml/min. The entire procedure requires about eleven minutes.

- Keep the disposable set filled with cold fluid during the entire procedure.



Power calibration screen, waiting to update

- The input and output temperature to the heat exchanger will be displayed. Wait for the DT value, the difference between input and output temperature to stabilize. When the system has stabilized, the UPDATE key will appear. Press UPDATE to complete the calibration. The display will return to the Calibration/Set-Up screen. The power module and pump are now calibrated.

G. ELECTROMAGNETIC COMPATIBILITY

This equipment has been designed and tested for compliance with IEC 60601-1-2 standards for its capacity to limit electromagnetic emissions and its ability to block the effects of EMI from external source.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference with other devices in the vicinity. If this equipment does cause interference with other device, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Ensure that other products used in the areas where patient monitoring and/or life-support is used comply with accepted emissions standards (EN55011).
- Try to maximize the distance between electromechanical devices
- Strictly limit exposure and access to portable radio-frequency sources, for example cellular phones and radio transmitters. Be aware that portable phones may periodically transmit even when in standby mode.
- Connect the equipment into an outlet on a circuit different from that which the other device(s) are connected. Maintain good cable management. Try not to route cables over electrical equipment. Do not intertwine cables.
- Do not use an extension power cord. Use the power cord supplied with the FMS2000.

H. FUSE

The fuse on the AC/DC supply marked F1 is rated as 1.25A, 250V, fast acting, 5x20mm.

I. CALL FOR SERVICE

Technical support can be reached at **800-397-4547** US/Canada, **978-663-0212** Worldwide. Before calling, please have the following ready:

- Serial number of the unit. The serial number is located on the label above the power receptacle.

Please do not return any units without first obtaining a Return Goods Authorization (RGA) number.